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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/171,740 | 04/20/99 | IGNATIUS | F 10391/003001 |

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HM22/0213

EXAMINER

WARE, T

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/171,740

Applicant(s)

IGNATIUS ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2000.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 22-39, 41-64, 66-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 40 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Receipt of supplemental information disclosure statement filed 10-31-00, request for extension of time and amendment both filed 11-17-00 is acknowledged. Claims 1 and 21 have been amended as requested. Claims 22-39, 41-64 and 66-67 are withdrawn from consideration as they are drawn to a non-elected invention. Claims 1-24, 40, and 65 are pending.

This application contains claims 22-39 , 41-64 and 66-67 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC ' 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-21, 40 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby et al (WO 94/15587; hereafter '587).

'587 teaches peptide-polymer ionic conjugate microparticles wherein the polymer is a polyester that is the same as the instant invention (paragraph bridging pages 4 and 5, paragraph bridging pages 6 and 7, Tables 1-3, 6, Example 11). The disclosed peptide is either LHRH or somatostatin. Example 11 of '587 teaches the instant

Art Unit: 1615

methods. Ionic conjugates are formed by dissolving a biodegradable polymer in a liquid, while a peptide (drug) is dissolved in another liquid. These liquids are essentially mixed to form the peptide-polymer ionic conjugate and added to acetone. In the paragraph bridging pages 4 and 5 and the paragraph bridging pages 6 and 7, '587 discloses that tetrahydrofuran (THF) or acetonitrile, or mixtures thereof is substituted for or with acetone. The acetone/peptide-polymer solution is then injected into water or alcohol (page 27, lines 3-4) in small droplets. The polymer/peptide complex then separates immediately into small particles which are then subjected to reduced pressure to remove residual acetone and centrifuged. '587 is silent as to the limitations of the instant claim 11, where the alcohol is maintained between about 0 C to about -30 C or 0 C and -70 C. However, since the process of '587 is otherwise the same as the instant claims and results in the formation of microparticles, the temperature limitations of the instant claim 11 are not afforded patentable weight absent a demonstration of criticality thereto. Furthermore, it would be within the gambit of one skilled in the art to form the microparticles at a temperature that allowed for the quickest, most easily formed, or desirable microparticles.

Response to Arguments

4. Applicant's arguments filed 11-17-00 have been fully considered but they are not persuasive. Applicants argue that the '587 reference does not teach that the first solution is added to the first liquid in the form of small droplets, adding that use of a teflon filter, as disclosed in the '587 reference on page 27, lines 3-4, to inject a second

Art Unit: 1615

solution does not produce small droplets. However, applicants have not provided evidence demonstrating such. Furthermore, syringes equipped with teflon filters are known in the art for injection of solutions via 0.2 μ teflon filters. Such filters can be fitted with needles for better control of the injection and, as noted in example 2 of the specification, would produce small droplets.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 6 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

Art Unit: 1615

numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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February 11, 2001